

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESAL PRICE
LITIGATION

MDL No. 1456

CIVIL ACTION: 01-CV-12257 PBS

THIS DOCUMENT RELATES TO:

Judge Patti B. Saris

*State of Montana v. Abbott Laboratories,
Inc., et al.*

D. Mont. Cause No. CV-02-09-H-DWM

*State of Nevada v. American Home Products
Corp., et al.*

D. Nev. Cause No. CV-02-0202-ECR

MEMORANDUM OF LAW OF NOVARTIS PHARMACEUTICALS
CORPORATION IN SUPPORT OF ITS MOTIONS TO DISMISS
THE SECOND AMENDED COMPLAINT OF THE STATE OF MONTANA
AND THE AMENDED COMPLAINT OF THE STATE OF NEVADA

INTRODUCTION

Novartis Pharmaceuticals Corporation ("NPC") was first named as a defendant in the Second Amended Complaint brought by the State of Montana ("Montana") against 21 pharmaceutical companies and company groups and was newly added as a defendant in the Amended Complaint brought by the State of Nevada ("Nevada," collectively with Montana, the "States") against 13 companies and company groups. In nearly identical language, the States assert causes of action for violations of their respective laws in connection with their overall claim that they and their citizens have incurred inflated costs for drugs as a result of two so-called "schemes" by defendants: (1) the "Best Price Scheme" by which "[m]anufacturers have misrepresented their Best Prices by failing to accurately account for their practices of offering free goods, volume discounts, credits, rebates, educational grants and other programs that lower the providers' actual cost of the drugs" and (2) the "AWP ["average wholesale price"] Inflation Scheme" "involving the fraudulent reporting of fictitious AWP's for certain prescription pharmaceuticals." Montana's Second Amended Complaint ("Mont. Cplt. ¶__") ¶¶7, 12; Nevada's Amended Complaint ("Nev. Cplt. ¶__") ¶¶7, 12. NPC joins in and incorporates by reference Defendants' Consolidated Motion and Memorandum of Law in Support of Defendants' Motion to Dismiss the State of Montana's Second Amended Complaint and the State of Nevada's Amended Complaint ("Def. Mem.") and memoranda of individual defendants, which demonstrate that the States' complaints must be dismissed. Each ground for dismissal applies to NPC. NPC demonstrates below additional grounds for dismissal of both complaints as to NPC.

ARGUMENT

THE COMPLAINTS MUST BE DISMISSED AS TO NPC FOR FAILURE TO PLEAD FRAUD AND STATE A CLAIM UNDER FED. R. CIV. P. 9(b) AND 12(b)(6).

Counts I and II of Montana's complaint allege violations of Montana's Deceptive Trade Practices Act (Mont. Code Ann. §§30-14-101-1414) in connection with alleged Best Price and AWP Inflation Schemes. Mont. Cplt. ¶¶654-67. Count III alleges Medicaid fraud (Mont. Code Ann. §53-6-160) and Count IV alleges violation of Montana's False Claims Act (Mont. Code Ann. §17-8-231), both for reporting allegedly inflated "Best Prices" to the federal Medicaid program, in turn causing Montana and its residents to pay inflated drug costs. Mont. Cplt. ¶¶668-91. Count V seeks punitive damages for such fraudulent conduct. *Id.* ¶¶692-93. Counts I-III of the Nevada complaint similarly allege violations of

state Deceptive Trade Practices law (NRS 598.0903 *et seq.*) as a result of the so-called Best Price and AWP Inflation Schemes. Nev. Cplt. ¶¶423-43. Count IV asserts violations of the state racketeering statute (NRS 207.400 *et seq.*) in connection with individual “Manufacturer-Publisher Enterprises” allegedly conducted for the purpose of carrying out the AWP Inflation Scheme. Nev. Cplt. ¶¶444-66. Count V asserts violation of state Medicaid fraud protections (NRS 422.540 *et seq.*; Nev. Cplt. ¶¶467-77) as a result of the schemes, and Count VI seeks punitive damages for the same alleged misconduct (*id.* ¶¶478-79). Because each of the States’ claims alleges acts of fraud, each is subject to Fed. R. Civ. P. 9(b) pleading requirements. *Hayduk v. Lanna*, 775 F.2d 441, 443 (1st Cir. 1985) (Fed. R. Civ. P. 9[b] applies to state law fraud claims alleged in federal court); *Varney v. R.J. Reynolds Tobacco Co.*, 118 F. Supp. 2d 63, 67 (D. Mass. 2000) (citing *Hayduk*, *inter alia*) (“Even in cases removed from state court, the adequacy of pleadings is measured by the federal rules.”).

It is “well settled” in the First Circuit that Rule 9(b) requires that the “time, place, and content of an alleged false representation” be pled with specificity. *Wayne Investment, Inc. v. Gulf Oil Corp.*, 739 F.2d 11, 13 (1st Cir. 1984) (citation omitted); *accord Suna v. Bailey Corp.*, 107 F.3d 64, 68, 73 (1st Cir. 1997); *see also Vicom, Inc. v. Harbridge Merchant Servs., Inc.*, 20 F.3d 771, 778 (7th Cir. 1994) (in a case involving multiple defendants, the complaint must inform each defendant of the specific alleged fraud by that particular defendant). Moreover, where fraud allegations are based merely on “information and belief” (e.g., Mont. Cplt. ¶615, Nev. Cplt. ¶395-96), the complaint also must “set forth a factual basis for such belief.” *U.S. ex rel. Walsh v. Eastman Kodak Co.*, 98 F. Supp. 2d 141, 147 (D. Mass. 2000) (Saris, J.) (citation omitted) (dismissing *qui tam* complaint alleging that vendors submitted invoices to hospitals that did not reflect discounts and credits – causing the hospitals to submit false claims for Medicare reimbursement – where the relator did not identify specific sales or claims for payment that were allegedly fraudulent and did not plead the source of his information or the reasons for his beliefs); *see also Wayne Investment, Inc.*, 739 F.2d at 13-14. As set forth below, the States’ Best Price and AWP claims and Nevada’s racketeering claim are not pled with the particularity mandated by Fed. R. Civ. P.

9(b) and do not otherwise state a claim under Fed. R. Civ. P. 12(b)(6); thus, both complaints must be dismissed as to NPC. *See also* Def. Mem. at Point III.

A. There Are No Best Price Allegations Specific To NPC.

There is not one allegation in either complaint specific to NPC in connection with the States' claim of fraudulent Best Price reporting. The States have not (i) pled the price allegedly reported by NPC as the Best Price for any drug, or who reported such Best Price or when, or how such reported Best Price is fraudulent; (ii) made any allegations relating to NPC in the "exemplary misconduct in the area of Best Price reporting" identified in the complaints (Mont. Cplt. ¶616, Nev. Cplt. ¶397); or (iii) set forth any specific facts as to how NPC allegedly excluded certain discounts and inducements to physicians, hid rebates, or otherwise failed to report Best Price. Because the complaints do not identify even a single incident of a false Best Price reported by NPC, the States "ha[ve] not met even a bare-bones Rule 9(b) test." *Walsh*, 98 F. Supp. 2d at 147 (citation omitted).

B. The States' AWP Claims Likewise Are Not Alleged With Any Specificity.

1. No AWPs are alleged for nine NPC drugs.

The AWP-based allegations in Montana's complaint pertaining to NPC (Mont. Cplt. ¶¶89-90, 496-503) and its Appendix A are identical to Nevada's (Nev. Cplt. ¶¶61-62, 317-24, App. A) and both suffer the same fatal infirmities. Although the States base their claims for relief against NPC on 30 NPC drugs allegedly subject to false AWP reporting (Mont. Cplt. ¶501; Nev. Cplt. ¶322), *nine of these drugs are not listed in Appendix A* – which purports to contain the AWPs for specific drugs from December 1997 to December 2002.¹ Indeed, the States have represented that "Appendix A . . . sets forth the fraudulent AWPs for each drug." Plaintiffs' Memorandum in Support of Plaintiffs' Joint Motion to Compel Discovery (Sept. 3, 2003), "Plaintiffs' Mem.," at 7. Thus, *the States concede that they have not pled the allegedly fraudulent AWP for the nine drugs omitted from Appendix A*. As this Court has held,

¹ The nine NPC drugs omitted from Appendix A are Diovan, Diovan HCT, Elidel, Famvir, Focalin, Rescula, Voltaren Ophthalmic, Zaditor and Zelnorm.

fraud claims based on named drugs without an identified fraudulent AWP must be dismissed. *In re Pharm. Indus. Average Wholesale Price Litig.*, 263 F. Supp. 2d 172, 194 (D. Mass. 2003) (Saris, J.); *see also* Def. Mem. at Point III.B.

2. The States fail to allege fraudulent AWPs for the remaining NPC drugs.

As for those NPC drugs listed in Appendix A, the States plead only the AWPs historically published from 1997 through 2002.² They do not, however, plead any specific facts supporting their conclusory allegations that NPC engaged in a scheme to inflate these AWPs or has used impermissible inducements to stimulate sales of its drugs. Likewise, the States fail to plead how any identified AWPs allegedly are fraudulent.³ As the Court stated to plaintiffs during the January 13, 2003 oral argument in connection with defendants' motion to dismiss the AWP multi-district litigation: "You've got to meet 9(b) requirements. You've got to particularize exactly what drugs, exactly what the fraud is" *In re Average Wholesale Price Pharm. Litig.*, Tr. of Oral Argument at 74 (Jan. 13, 2003); *see also In re Pham. Indus. Average Wholesale Price Litig.*, 263 F. Supp. 2d at 194. The States do not meet this test as to NPC.⁴

Clearly, the States' unsupported allegation that defendants engaged in a "scheme" to inflate AWP does not suffice to meet Rule 9(b) requirements. As the *Hayduk* court held, "mere allegations of fraud, corruption or conspiracy, averments to conditions of mind, or referrals to plans and schemes are too conclusional to satisfy the particularity requirement, no matter how many times such accusations are repeated." 775 F.2d at 444 (citations omitted); *see also Varney*, 118 F. Supp. 2d at 68 (citing *Hayduk*

² Notably, the December 2002 AWPs for NPC drugs quoted by plaintiffs in Appendix A are substantially in excess of the AWPs published by NPC on its price lists for those same drugs.

³ The States allege only that there was a government investigation of an inflated AWP in connection with an NPC drug Aredia (Mont. Cplt. ¶503, Nev. Cplt. ¶324) – which is *not* one of the 30 NPC drugs for which the States purport to seek relief, which is not included in Appendix A, and which allegation apparently was included solely for what the States perceive as its prejudicial value.

⁴ Seven of the NPC drugs named in the complaints are multiple source drugs (*see Exhibit A*); all claims relating to these drugs also should be dismissed for the same reasons that claims relating to multiple source drugs were dismissed from the AWP multi-district litigation (263 F. Supp. 2d at 194). *See also* Def. Mem. at Point III.B.

and Rule 9[b]) ("Pleadings which portray a conspiracy to defraud or conceal may not be painted in broad strokes; they must state the factual foundations of that claim with particularity."). In sum, the States' claims against NPC are fatally flawed and must be dismissed.

C. Nevada's Racketeering Claim Also Fails For Lack Of Specificity.

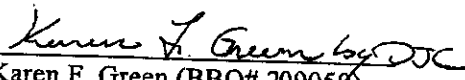
Nevada's Count IV racketeering claim is predicated on fraud-based state claims – *i.e.*, obtaining money under false pretenses and insurance fraud (Nev. Cplt. ¶459) – and, thus, also is subject to Rule 9(b) pleading requirements. *Hayduk*, 775 F.2d at 443. Once again, Nevada fails to plead any particulars regarding NPC's allegedly fraudulent conduct to support the racketeering claim; no facts are alleged, for example, as to how NPC deliberately overstated AWP's, provided free samples of drugs to medical providers, or engaged in any other misconduct. Nevada thus fails to plead racketeering predicate acts as to NPC with the specificity mandated by Fed. R. Civ. P. 9(b) and otherwise fails to state a claim upon which relief may be granted.⁵

CONCLUSION

For the foregoing reasons, and those in Defendants' Consolidated Memorandum and individual defendants' memoranda, the Court should dismiss with prejudice all claims as to NPC.

Dated: Boston, Massachusetts
September 15, 2003

Of counsel:
Jane W. Parver
KAYE SCHOLER LLP
425 Park Avenue
New York, New York 10022
Telephone: (212) 836-8000
Facsimile: (212) 836-7153


Karen F. Green (BBO# 209050)
HALE AND DORR LLP
60 State Street
Boston, Massachusetts 02109
Telephone: (617) 526-6000
Facsimile: (617) 526-5000

Attorneys for Novartis Pharmaceuticals Corp.

⁵As demonstrated in Def. Mem. (Point II.B), the racketeering claim also fails for the additional reasons that Nevada (i) lacks standing to sue for monetary damages and (ii) does not allege a viable RICO enterprise.

EXHIBIT A

**Multiple Source NPC Drugs Identified in
the State of Montana's Second Amended Complaint (§§501, 503)
and the State of Nevada's Amended Complaint (§§322, 324)**

1. Aredia
2. Clozaril
3. CombiPatch
4. Parlodel
5. Ritalin Hydrochloride
6. Tegretol
7. Vivelle

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY)
AVERAGE WHOLESAL PRICE)
LITIGATION)

MDL No. 1456

CIVIL ACTION: 01-CV-12257 PBS

THIS DOCUMENT RELATES TO:

Judge Patti B. Saris

State of Montana v. Abbott Laboratories,
Inc., et al.

D. Mont. Cause No. CV-02-09-H-DWM

State of Nevada v. American Home Products
Corp., et al.

D. Nev. Cause No. CV-02-0202-ECR

ORDER

For the reasons set forth in the Memorandum of Law of Novartis Pharmaceuticals Corporation in Support of Its Motion to Dismiss the Second Amended Complaint of the State of Montana and the Amended Complaint of the State of Nevada, IT IS HEREBY ORDERED as follows: The Court **ALLOWS** the motion to dismiss and dismisses with prejudice as to Novartis Pharmaceuticals Corporation: (1) all claims in the Second Amended Complaint of the State of Montana and (2) all claims in the Amended Complaint of the State of Nevada.

Dated: _____, 2003

PATTI B. SARIS, USDJ